DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-87, drawn to a measurement system for detecting a predetermined condition of a patient's ear indicative of a certain disease.

Group II, claim(s) 88, drawn to a system for determining a patient's condition.

Group III, claim(s) 89, drawn to an optical probe.

Group IV, claim(s) 90, 93, 94 drawn to a control unit.

Group V, claim(s) 91-92, drawn to an optical measuring unit.

Group VI, claim(s) 95, drawn to a method of processing spectral measured data.

Group VII, claim(s) 96-99, drawn to a method for detecting an SOM or AOM condition.

Group VIII, claim(s) 100, drawn to a method for determining a patient's condition.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of the eight groups lack the same corresponding special technical features as:

The special technical feature of the Group I invention is a measurement system generating two different wavelengths and determining a relation between *measured light responses* and reference data;

The special technical feature of the Group II invention is a measurement system measuring spectral data and applying a *predetermined model* to determine a parameter value and determine an association between the *determined parameter value* and the reference data (vs. between the measured light responses and the reference data and without applying a predetermined model such as in Group I);

The special technical feature of the Group IV invention is a *control unit* that *normalizes* data by a reference spectrum and applies a *predetermined model* to determine a parameter value and determines an association between the *determined parameter value* and the reference data (vs. a measurement system that determines a relationship between the measured light responses and the reference data, that does not normalize, and that does not apply a predetermined model such as in Group I; vs. a measurement system that does not normalize such as in Group II);

The special technical feature of the Group VI invention is a *method* of processing spectral measured data by *normalizing* measured data *to obtain a relative spectrum* and determine an association between the *relative spectrum* and reference data (vs. a system that determines a relationship between measured light responses and the reference data and that does not normalize such as in Group I; vs. a system that does not normalize, that uses a predetermined model and that determines an association between the determined parameter value and the reference value such as in Group II; vs. a system that uses a predetermined model and that normalizes by a reference spectrum such as in Group IV);

The special technical feature of the Group VIII invention is a *method* for determining a patient's condition wherein a *predetermined model* is applied to determine a parameter value and generating an association between the *determined parameter value* and reference data (vs. a system that determines a relationship between measured light responses and the reference data and that does not use a predetermined model such as in Group I; vs. a system such as in Group II; vs. a system that normalizes such as in Group IV; vs. using normalization and not using a predetermined model such as in Group VI);

The special technical feature of the Group VII invention is a *method* for detecting an *SOM or AOM condition* of a patient's ear by illuminating the ear by at least two wavelengths (vs. obtaining measurement data and using predetermined reference data and determining associations or relationships between data and predetermined reference data of Groups I, II, IV, VI, and VIII);

The special technical feature of the Group III invention is an *optical probe* with a *speculum*;

The special technical feature of the Group V invention is an *optical measuring unit* with a *plug*;

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I:

Species A1 - using wavelengths that detects an AOM condition
Species A2- using wavelengths that detect a change in hemoglobin level
Species A3 - using wavelengths that detect a SOM condition

Species B1 - wherein the selected range of predetermined light includes a range of 500-650 nm
Species B2 - wherein the selected range of predetermined light includes a range of 800-950 nm

Species C1 - wherein the objective comprises an eyepiece ocular
Species C2 - wherein the objective comprise a suitable camera

For Group VII:

Species A1 - illuminating by at least two wavelengths, the first wavelength is substantially absorbable by water or is substantially transmittable by water, the second wavelength being partially absorbable by water
Species A2 - illuminating by at least three wavelengths, the first wavelength is substantially absorbable by water and substantially non-absorbable by hemoglobin, or is substantially transmittable by water and substantially non-absorbable by hemoglobin, the second wavelength being partially absorbable by water and highly absorbable by hemoglobin

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

The claims are deemed to correspond to the species listed above in the following manner:

Group I:
Species A1: Claims 3, 19, 20, 21
Species A2: Claims 4, 8
Species A3: Claim 7

Species B1: Claims 28, 30
Species B2: Claim 29

Species C1: Claims 65, 73
Species C2: Claims 66, 74

The following claim(s) are generic for Group I: 1, 2, 5, 6, 9-18, 22-27, 31-64, 67-72, 75-87.

Group VII:
Species A1: Claims 96-98
Species A2: Claims 99

The following claim(s) are generic for Group VII: None.

REQUIREMENT FOR UNITY OF INVENTION

4. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical

relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

5. As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143), (ii) an election of species if Group VII is chosen, or multiple elections of species if Group I is chosen to be examined even though the requirement may be traversed (37 CFR 1.143) and (iii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Examiner, Art Unit 3768